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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,270	09/05/2003	Fritz Eckstein	00-838-Q	7134

7590 10/25/2006

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EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

14

Office Action Summary	Application No. 10/656,270	Applicant(s) ECKSTEIN ET AL.	
	Examiner Dana Shin	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-16 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-16 and 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communication filed on September 29, 2006.

Currently, claims 1-2, 5-16, and 20-26 are pending. Applicants have cancelled claims 3-4 and 17-19.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Terminal Disclaimer

The terminal disclaimer filed on September 29, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 5,672,695 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112-Written Description

Claims 1-2, 5-16, and 20-26 remain rejected under 35 U.S.C. 112, first paragraph, as failed to comply with the written description requirement for the reasons of record as set forth in the Office action mailed on September 15, 2006 and for the reasons stated below.

Applicant's arguments filed on March 6, 2006 have been fully considered but they are not persuasive.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and /or chemical properties, functional characteristics, structure/function correlation, or any combination thereof.

Although applicant has amended the instant claims by replacing the term "RNA molecule" by "oligoribonucleotide", the claimed subject matter "oligoribonucleotide" is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of all the species represented by the term "oligoribonucleotide" at the time the application was filed. As originally filed, the instant specification provides adequate description only for ribozymes, especially hammerhead ribozymes. Further, the instant disclosure does not recite any other species embraced by the term "oligoribonucleotide", such as antisense oligoribonucleotide or short interfering oligoribonucleotide (siRNA). In the absence of positive recitations of such specific species of the instantly claimed oligoribonucleotide, one skilled in the relevant art would ascertain that the

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inventors were not in possession of all types of species of the recited oligoribonucleotides at the time the instant application was filed in 1990.

In view of the foregoing, it is concluded that the ribozyme species disclosed in the instant specification are not representative of the genus encompassed by the broadly recited "oligoribonucleotide".

Claim Rejections - 35 USC § 112-Enablement

Claims 22 and 23 stand rejected under 35 U.S.C. 112, first paragraph, as failed to comply with the enablement requirement for the reasons of record as set forth in the Office action mailed on September 15, 2006 and for the reasons stated below.

Applicant's arguments filed on March 6, 2006 have been fully considered but they are not persuasive.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'." (*Wands*, 8 USPQ2d 1404). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction

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provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Although applicants amended the broad claim, claim 14, from which both claims 22 and 23 depend, the method of increasing stability of ribozymes having either 2'-deoxy-2'-fluoro adenosine nucleotides or 2'-deoxy-2'-fluoro^o guanosine nucleotides, in addition to having 2'-deoxy-2'-fluoro uridine and cytidine nucleotides as recited in claim 14 is not considered enabled based on the totality of factors listed above. In particular, as stated in the previous Office action on page 5, the instantly claimed method was considerably nascent at the time the instant invention was made in October, 1990. Moreover, the amount of direction provided by inventors through working examples in the instant specification is not sufficient to overcome the art-recognized unpredictability in light of the nascent nature of the invention at the time of original filing of the instant application. In view of the foregoing, undue experimentation would have been necessitated in order for one skilled in the art to practice the invention commensurate in scope with claims 22 and 23.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

Handwritten signature of Jane Zara, consisting of a stylized 'J' and 'Z' followed by 'TC1600'.

JANE ZARA, PH.D.
PRIMARY EXAMINER